

equivalent to 12,600 International Units of estrone per cubic centimeter of solution, differed from the strength which the article was represented to possess, namely, an amount of natural estrogens from pregnant mares' urine equivalent to 20,000 International Units of estrone per cubic centimeter of solution.

Misbranding, Section 502 (a), the label statement "Natural Estrogens from pregnant mares' urine equivalent to 20,000 international units of estrone per cubic centimeter" was false and misleading as applied to the article, which contained per cubic centimeter of solution an amount of natural estrogens from pregnant mares' urine equivalent to 12,600 International Units of estrone.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 22, 1953. Default decree of condemnation and destruction.

**4093. Adulteration and misbranding of estrogenic substances. U. S. v. 20 Cartoned Vials \* \* \*. (F. D. C. No. 34896. Sample No. 62341-L.)**

**LIBEL FILED:** March 17, 1953, Eastern District of Missouri.

**ALLEGED SHIPMENT:** On or about January 12, 1953, from Jersey City, N. J.

**PRODUCT:** 20 cartoned 20 cc. vials of *estrogenic substances* at St. Louis, Mo.

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the actual strength of the article, namely, an amount of natural estrogens from pregnant mares' urine equivalent to 13,400 International Units of estrone in each cubic centimeter of solution, differed from the strength which the article was represented to possess, namely, an amount of natural estrogens from pregnant mares' urine equivalent to 20,000 International Units of estrone in each cubic centimeter.

Misbranding, Section 502 (a), the label statement "Natural Estrogens from pregnant mares' urine equivalent to 20,000 international units of estrone per cubic centimeter" was false and misleading as applied to a product which contained per cubic centimeter of solution an amount of natural estrogens from pregnant mares' urine equivalent to less than 20,000 International Units of estrone, namely, not more than 13,400 International Units of estrone per cubic centimeter.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: April 10, 1953. Default decree of condemnation and destruction.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\***

**4094. Misbranding of cigarettes. U. S. v. 46 Cartons, etc. Answer filed by claimant denying that product was a drug. Decision for the Government. Decree of condemnation. (F. D. C. No. 33295. Sample No. 38038-L.)**

**LIBEL FILED:** June 13, 1952, District of New Jersey.

**ALLEGED SHIPMENT:** On or about February 29, 1952, by G. A. Georgopulo & Co., from New York, N. Y.

**PRODUCT:** 46 cartons, each containing 10 packages, of *cigarettes* at Jersey City, N. J., together with a number of leaflets entitled "How Fairfax Cigarettes may help you." The article was represented, in the leaflet, to contain tobacco, triethylene glycol, and chlorophyll.

\*See also Nos. 4084, 4086, 4091-4093.

LABEL, IN PART: (Package) "Fairfax Cigarettes \* \* \* Sterling Tobacco Corp., New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a) certain statements in the above-mentioned leaflet accompanying the article were false and misleading. The statements represented and suggested that the article would be effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, meningitis, tuberculosis, mumps, otitis media (middle ear infection), and meningopneumonitis psittacosis (parrot fever), and that it would be innocuous for persons suffering from circulatory diseases, high blood pressure, and various heart conditions. The article would not be effective in preventing the conditions stated and implied, and it was not innocuous for persons in the categories mentioned.

DISPOSITION: On September 3, 1952, the Sterling Tobacco Corp. appeared as claimant and filed an answer denying that the product was a drug and that it was misbranded. Interrogatories were served upon the claimant by the Government. The interrogatories were answered in part by the claimant, after which, pursuant to an agreement between the parties, the case was submitted to the court for determination of the issue of whether or not the product was a drug.

On June 10, 1953, the court handed down the following opinion:

MEANEY, *District Judge*: "This matter is submitted on the following agreed set of facts:

"The claimant introduced into interstate commerce 46 cartons of 'Fairfax cigarettes' with 51 accompanying leaflets entitled 'How Fairfax Cigarettes may help you,' all of which the libellant caused to be seized under the provisions of 21 U. S. C. 301 et seq. (1946 Ed.). The libel, as amended, alleges that the cigarettes are a drug and were misbranded when introduced into and while in interstate commerce.

"It is agreed by the parties hereto that the only question to be decided is whether the seized article is a drug within the meaning of the Federal Food, Drug and Cosmetic Act, above cited. It is further agreed that if the seized article be found not to be a drug, the libel should be dismissed for lack of jurisdiction of the subject matter. If, however, it be found to be a drug, misbranding is conceded and a decree of condemnation will be entered.

"The term 'drug' in this connotation is defined in the Federal Food, Drug and Cosmetic Act as follows:

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts or accessories. (21 U. S. C. A. 321.)

"Because of the wording of this provision, with particular reference to (g) (2), it is important to examine the representations of the circular accompanying the article in question. The libellant contends that the leaflet accompanying the article suggests and represents that the article is effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis (parrot fever). Libellant further contends that claimant represents that the smoking of these cigarettes is innocuous for persons suffering from circulatory diseases, high blood pressure and various heart conditions. There is no doubt that the leaflets accompanying the cigarettes fall within

the meaning of labeling in the instant case. *Kordel v. United States*, 335 U. S. 345. If there be an indication of intent to use the article for the cure or mitigation, or treatment or prevention of disease in man, then clearly the subject matter of the libel is to be considered a drug within the meaning of the Act. As is said in Senate Report No. 361, 74th Congress, 1st Session, 'The manufacturer of the article through his representations in connection with its sale, can determine the use to which the article is to be put.'

"Against this analysis of the leaflets the claimant contends that its only substantial assertion concerning the cigarettes is that they increase one's smoking pleasure. If this be so, then the extensive references to 'miracle vapor' and its seeming effects in the reduction of the frequency of respiratory diseases, and the somewhat more than casual references to the diseases aforementioned, would appear to have no other purpose than to mislead the unwary. In those fields where there is heavy competition, hucksters, as the over impulsive advertising copy writers seem to be slightly denominated in the trade, vie with each other in the composition of extravagant descriptions of the beneficial qualities of their product, or in insinuations or indirectness from which the untutored mind would infer extraordinary ameliorative results. Exactness, completely truthful statements and objective verisimilitude are frequently subordinated to blatant, spectacular, suggestive or dubious representations in order to break down sales resistance or to create a demand for a product hitherto not found necessary to the happiness or the well-being of the general public.

"This is certainly not the first occasion on which cigarette advertisers and representatives of the public have clashed. See *Federal Trade Commission v. Liggett & Myers Tobacco Company*, 108 F. Supp. 573, 577 (S. D. N. Y. 1952). Perhaps in a field where, generally speaking, competition is met by advertising and labeling rather than by price or even perhaps by substantial differences in quality, such conflicts are almost inevitable as manufacturers tread near the statutory boundary. Certainly, Congress in drawing this boundary had in mind that the public should be adequately and truthfully informed as to what it is purchasing. The Federal Food, Drug and Cosmetic Act must be construed so as to effectuate the purpose of protecting the buying public, which is largely beyond self-protection in the circumstances of modern life. 62 *Cases of Jam v. United States*, 340 U. S. 593, 596 (1951); *Kordel v. United States*, *supra*: *United States v. Dotterweich*, 320 U. S. 277, 280 (1943).

"The question, therefore, is whether the public, having in mind the specious statements of the leaflets, would buy Fairfax cigarettes primarily for smoking enjoyment or with the hope of mitigating, curing or preventing disease.

"In *Bradley v. United States*, 264 Fed. 79 (C. C. A. 5, 1920), mineral water was sold in interstate commerce with the labeling, 'Recommended in the treatment of Bright's disease' and other named diseases. The court was called upon to decide whether these words, properly construed, meant that the water had curative or therapeutic qualities. Claimant argued that the label made no statement regarding these qualities. The court held, however, that the use of the above-quoted words in the label 'could only mean that the use of the water in the treatment of the diseases named would effect a cure or alleviation of such diseases; otherwise, why recommend it?' (p. 81).

"\* \* \* The contention is made that the water condemned in this case is not a drug, within the meaning as used in the act. \* \* \* As Justice Hughes says, in *Seven Cases v. U. S.* 239, U. S. 517 \* \* \* "That false and fraudulent representations may be made with respect to the curative effect of substances is obvious," and when so made of water it seems to us that it would be trifling to say that water ordinarily is not a drug in the true meaning of the word, and therefore does not fall within the condemnation of \* \* \* the act. If the allegations of the libel are true, the claimant has put the substance, water, in interstate commerce with the recommendation that it possesses certain elements or ingredients which are curative, or at least alleviative, for the diseases named in the label. He will not be heard now to say the substance recommended is water, and not a drug. Such a construction would nullify the act of Congress.' (pp. 81, 82).

"Although the case at bar may be less obvious, the principles involved are nevertheless the same as those of the *Bradley* case. If claimant's labeling was such that it created in the mind of the public the idea that these cigarettes could be used for the mitigation or prevention of the various named diseases,

claimant cannot now be heard to say that it is selling only cigarettes and not drugs.

"On this point legislative intent is clear. 'The use to which a product is to be put will determine the category into which it will fall. If it is to be used only as a food it will come within the definition of food and no other. If it contains nutritive ingredients but is sold for drug use only, as clearly shown by the labeling and advertising, it will come within the definition of drug, but not that of food. If it is sold to be used both as a food and for the prevention or treatment of disease it would satisfy both definitions and be subject to the substantive requirements for both. The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product.' (Senate Report No. 361, 74th Congress, 1st Session from the Committee on Commerce Report to accompany S. 5).

"How, then, has the manufacturer in the case at bar represented his product to the public? What is the nature and import of the labeling as shown by the leaflet?

"Claimant, understandably, does not believe it is selling drugs. It admits that the product has none of the curative or preventive powers implied in the leaflet. But throughout the leaflet claimant has tried to capture a share of the cigarette market by a subtle appeal to a natural and powerful desire on the part of us all to avoid the infectious diseases or ailments therein mentioned. Should the buying public or some portion of it turn to Fairfax cigarettes, it would most likely do so because of the means claimant has used to bring the cigarettes to public attention. It is not likely that the buying public would ordinarily carefully study or weigh each word in the leaflet. 'The ultimate impression upon the mind of the reader arises from the sum total of not only what it said but also of all that is reasonably implied.' *Aronberg v. Federal Trade Commission*, 132 F. 2d 165, 167 (C. C. A. 7, 1942). The clear import of the leaflet is at least that the smoking of the cigarettes will make it less likely that the smoker will contract colds or other virus infections. This is enough to bring the product within the statutory meaning of 'drug.' If claimant wishes to reap the reward of such claims, let it bear the responsibility as Congress has seen fit to impose it. *United States v. Dotterweich*, *supra*: cf. *Barnes v. United States*, 142 F. 2d 648 (D. C. A. 9, 1944)."

Pursuant to the above opinion, the court, on June 29, 1953, entered a decree of condemnation and ordered that the product be destroyed. On September 9, 1953, with the consent of the parties, an amended decree was entered providing for the release of the product under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

**4095. Misbranding of Yo-Zyme yogurt tablets. U. S. v. 63 Bottles, etc. (F. D. C. No. 33313. Sample Nos. 1162-L, 1163-L.)**

**LIBEL FILED:** July 7, 1952, Southern District of Florida.

**ALLEGED SHIPMENT:** On or about March 17, 1952, by MacDonald Laboratories, Inc., from St. Paul, Minn.

**PRODUCT:** 63 150-tablet bottles and 86 500-tablet bottles of *Yo-Zyme yogurt tablets* at Orlando, Fla., together with a number of mailing cards entitled "Yo-Zyme" and a number of leaflets entitled "The Story of Yo-Zyme" and "Yo-Zyme For Health and Vitality."

Examination showed that the product contained a small number of viable streptococci and lactobacilli organisms.

**LABEL, IN PART:** (Bottle) "Yo-Zyme Yogurt Cpd. Tablets" or "Yo-Zyme Yogurt Cpd. Healthfood Tablets."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the bottle labels and the above-mentioned